Clinical Development

Risperidone

RISINT061

Anonymisation Data Derivation Specification Document

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1. Datasets

1.1. Specifications Introduction

This specification for each dataset will be in two parts

- Dataset description
- Variables within dataset

Part I: Dataset description

Dataset	Name of dataset
Description	Short description
Unique Identifier	Unique key

Part II: Variables within dataset

Variable	SAS variable name
Type	Character or Numeric
Label	SAS variable label
Comments	Variable source derivation explanation if variable derived.

1.2. Guidelines for Preparing Data

The data will be provided according to the De-identified/ Anonymisation data guidelines standards with the following exceptions:

- Subject initials will not be provided.
- Investigator Information will not be provided.
- Date of birth will not be provided.

- Age at trial start date will be calculated and grouped in intervals of ten years to protect PII as per HIPAA rules. A deidentified age variable will be created in which a new age is randomly selected within the original interval. Original minimum and maximum values will be used as limits for sampling from the smallest and largest age groups.
- Height will be converted to centimeters and grouped in intervals of 10 cm to protect PII as per HIPAA rules. A deidentified height variable will be created in which a new height is randomly selected within the original interval. Original minimum and maximum values will be used as limits for sampling at the smallest and largest height groups.
- Weight will be converted to kilograms and grouped to protect PII as per HIPAA rules. A deidentified weight variable will be created in which a new weight is randomly selected within the original interval. Original minimum and maximum values will be used as limits for sampling from the smallest and largest weight groups.
- Patient identification numbers will be assigned in a random manner so they are not matching the patient identification numbers that were used in the actual trial.
- Severe adverse event reference number will not be provided.
- Free text verbatim terms will not be provided.
- Free text summary terms will not be provided.
- "Other" free text terms will not be provided.
- Drug Record Number will not be provided.
- Drug Sequence Number will not be provided.
- Accession Number will not be provided.
- Vial and Bottle number will not be provided.
- Central Lab Sample Identifier will not be provided.
- Central Lab Batch Identifier will not be provided.
- Vendor Panel Comments will not be provided.
- Vendor Test Specific Comments will not be provided.
- Lab Name information will not be provided.
- A date offset (DATE.OFFSET) will be randomly created for every individual in the dataset and used to de-identify all dates in the data.
- Completely missing variables those are not annotated in CRF will not be included in the De-Identified datasets.
- The following tables are not provided: code, invest, ivrs, plares, randgrp, remark, trllist, trlrand

1.3. Data Domains

1.3.1. SUBJCHAR

Dataset	SUBJCHAR
Description	Subject characteristics
Unique identifier	DCRFID

Variable	Type	Label	Comments
TRIAL	character	TRIAL ID.	Collected at CRF.
CRFID	character	CRF ID	Suppressed all records to protect PII.
INITIALS	character	SUBJECT INITIALS	Suppressed all records to protect PII
MEDNO	double	MEDICATION NO.	Suppressed all records to protect PII
INVEST	character	MAIN INVEST.	Suppressed all records to protect PII
ZINVEST	double	MAIN INVEST.	Suppressed all records to protect PII
COINV	character	INVESTIGATOR WHO SIGNED CRF	Suppressed all records to protect PII
ZCOINV	double	INVESTIGATOR WHO SIGNED CRF	Suppressed all records to protect PII
BIRTH_D	double	BIRTH DATE	Suppressed all records to protect PII
SEX	character	SEX	Collected at CRF.
RACE	character	RACE	Suppressed all records to protect PII.
HEIGHT	double	HEIGHT	Suppressed all records to protect PII
HEIGHT_U	character	HEIGHT UNIT	Collected at CRF.
SCSCHIZO	double	AGE AT DIAGNOSIS OF SCHIZOPHRENIA	Suppressed all records to protect PII
SCPREVPS	double	NUMBER OF PREVIOUS PSYCH.HOSP.	Suppressed all records to protect PII
ELIGIBLE	character	SUBJECT ELIGIBILITY	Collected at CRF.
INIT_B	character	INITIALS RANDOMIZED PERIOD BOOK	Suppressed all records to protect PII

BREAK	character	CODE BROKEN ?	Collected at CRF.
BREAK_D	double	DATE CODE BREAKING	Suppressed all records to protect PII
BREAK_V	character	REASON CODE BREAKING	Suppressed all records to protect PII
DISCVIS	character	D/C VISIT	Collected at CRF.
DRYRUN	character	DRY-RUN READY	Collected at CRF.
ENTRYCOM	character	ENTRY COMPLETED	Collected at CRF.
BATCHNO	double	BATCH NO.	Collected at CRF.
NARRAT	character	NARRATIVES	Collected at CRF.
DCRFID	integer	PATIENT NUMBER ASSIGNED FOR DE-IDENTIFICATION	Randomly assigned patient number for de-identification
DHEIGHT	integer	DE-IDENTIFIED HEIGHT	Grouped and randomly sampled within group to protect PII
DHEIGHTGP	integer	DE-IDENTIFIED HEIGHT GROUP	Aggregated height to three groups
DZINVEST	integer	DE-IDENTIFIED MAIN INVEST.	Randomly assigned investigator number for de-identification
DZCOINV	Integer	DE-IDENTIFIED INVESTIGATOR WHO SIGNED CRF	Randomly assigned co-investigator number for de-identification
DRACE	Character	DE-IDENTIFIED RACE	Small groups pooled in 'other'
DDIAGDURN	integer	DE-IDENTIFIED DIAGDURN	Grouped and randomly sampled within group to protect PII
DIAGDURNGP	character	DIAGNOSIS DURATION GROUP	Calculated duration and aggregated in 10-year groups
DXAGE	Integer	DE-IDENTIFIED XAGE	Grouped and randomly sampled within group to protect PII
DXAGEGROUP	character	DE-IDENTIFIED XAGEGROUP	Aggregated age in 10-yr groups
DSCSCHIZO	integer	DE-IDENTIFIED AGE AT DIAGNOSIS OF SCHIZOPHRENIA	Calculated from de-identified age and duration
DSCPREVPS	double	DE-IDENTIFIED NUMBER OF PREVIOUS PSYCH. HOSP.	Aggregated to two groups
DBREAK_D	date	DE-IDENTIFIED DATE CODE BREAKING	Applied subject specific randomly sampled offset to dates to protect PII
DCOUNTRY	character	DE-IDENTIFIED COUNTRY	Aggregated to continent level.

1.3.2. ADMMED

Dataset	ADMMED
Description	MEDICATION ADMINISTRATION
Unique identifier	DCRFID

Variable	Type	Label	Comments
TRIAL	character	TRIAL ID.	Collected at CRF.
CRFID	character	CRF ID	Suppressed all records to protect PII.
PHASE	character	TRIAL PHASE	Collected at CRF.
SEGMENT	double	SEGMENT	Collected at CRF.
BOX	character	BOX	Collected at CRF.
AMFROM_D	double	ADMIN. FROM DATE	Suppressed all records to protect PII.
AMFROM_T	double	ADMIN. FROM TIME	Collected at CRF.
AMTO_D	double	ADMIN. TO DATE	Suppressed all records to protect PII.
AMDOSE	character	DOSE	Collected at CRF.
ZAMDOSE	double	DOSE	Collected at CRF.
AMDOSE_U	character	DOSE UNIT	Collected at CRF.
NUMFORM	double	UNITS PER ADMIN.	Collected at CRF.
AMFREQ	character	ADMIN. FREQ.	Collected at CRF.
AMSCHED	character	ADMINISTRATION SCHEDULE	Collected at CRF.
AMREAS	character	REGIMEN CHANGE REASON	Collected at CRF.
ZAMREAS	character	REGIMEN CHANGE REASON	Collected at CRF.
AMSITE	character	ADMIN. SITE	Collected at CRF.
DAMTO_D	double	DE-IDENTIFIED ADMIN. TO DATE	Applied subject specific randomly sampled offset to protect PII
DAMFROM_D	double	DE-IDENTIFIED ADMIN. FROM DATE	Applied subject specific randomly sampled offset to protect PII
DCRFID	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification

1.3.3. AE

Dataset	AE
Description	ADVERS EVENT
Unique identifier	DCRFID

Variable	Type	Label	Comments
TRIAL	character	TRIAL ID.	Collected at CRF.
CRFID	character	CRF ID	Suppressed all records to protect PII.
AESEQNO	double	AE SEQ.	Collected at CRF.
AE_V	character	AE (VERB.)	Suppressed all records to protect PII.
AEINCL	character	AE INCLUDED TERM	Suppressed all records to protect PII.
PHASE	character	TRIAL PHASE	Collected at CRF.
AEFROM_D	double	AE FROM DATE	Suppressed all records to protect PII.
AEFROM_C	character	AE FROM CODE	Suppressed all records to protect PII.
AETO_D	double	AE TO DATE	Suppressed all records to protect PII.
AETO_C	character	AE TO CODE	Suppressed all records to protect PII.
AESEV	character	AE SEVERITY	Collected at CRF.
ZAESEV	double	AE SEVERITY	Collected at CRF.
AEACT	character	AE ACTION TAKEN	Collected at CRF.
ZAEACT	double	AE ACTION TAKEN	Collected at CRF.
AECONRX	character	AE CO-RX START	Collected at CRF.
ZAECONRX	double	AE CO-RX START	Collected at CRF.
AERELAT	character	AE DRUG RELATION	Collected at CRF.
ZAERELAT	double	AE DRUG RELATION	Collected at CRF.
AEOUT	character	AE OUTCOME	Suppressed all records to protect PII.
ZAEOUT	double	AE OUTCOME	Suppressed all records to protect PII.
AESER	character	AE SERIOUSNESS	Collected at CRF.

ZAESER	double	AE SERIOUSNESS	Collected at CRF.
SAEREFNO	character	SERIOUS AE REF.NO	Suppressed all records to protect PII.
AESOC	character	AE SYSTEM ORGAN CLASS	Collected at CRF.
AEWHONUM	character	AE WHO CODE	Suppressed all records to protect PII.
AEPREF	character	ADVERSE EVENT PREFERRED TERM	Suppressed all records to protect PII.
AESOC1	character	AE SYSTEM ORGAN CLASS 1	Collected at CRF.
AESOC2	character	AE SYSTEM ORGAN CLASS 2	Collected at CRF.
AESOC3	character	AE SYSTEM ORGAN CLASS 3	Collected at CRF.
DAEFROM_D	double	DE-IDENTIFIED AE FROM DATE	Applied subject specific randomly sampled offset to protect PII
DAETO_D	double	DE-IDENTIFIED AE TO DATE	Applied subject specific randomly sampled offset to protect PII
DCRFID	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification
DAEPREF	character	DE-IDENTIFED AE PREFERRED TERM	Aggregated sensitive terms to MedDRA SOC. Retained non-sensitive terms.
DAEOUT	character	DE-IDENTIFIED AE OUTCOME	Masked sensitive outcome. Retained non-sensitive outcomes.
DZAEOUT	Double	DE-IDENTIFIED AE OUTCOME	Masked sensitive outcome. Retained non-sensitive outcomes.

13.4. BANRES

Dataset	BANRES
Description	BIOANALYSIS RESULTS
Unique identifier	DCRFID

Variable	Type	Label	Comments
TRIAL	character	TRIAL ID.	Collected at CRF.
LABINTNO	character	LABORATORY INTERNAL NO.	Suppressed to protect PII
SPECIMEN	character	SPECIMEN	Collected at CRF.
SUBST	character	SUBSTANCE	Collected at CRF.
BRVAL	double	BAN MEASUREMENT	Collected at CRF.
BRVAL_V	character	BAN MEASUREMENT (VERB.)	Collected at CRF.
BRVAL_U	character	UNIT	Collected at CRF.
BRQUANT	character	LIMIT OF QUANTIFICATION	Collected at CRF.

1.3.5. COTHER

Dataset	COTHER
Description	CONCOMITANT THERAPHY
Unique identifier	DCRFID

Variable	Type	Label	Comments
TRIAL	character	TRIAL ID.	Collected at CRF.
CRFID	character	CRF ID	Suppressed all records to protect PII.
CTSEQNO	double	CO-RX SEQ.	Collected at CRF.
CONRX_V	character	CO-RX (VERB.)	Suppressed all records to protect PII.
CONRX	character	CO-RX	Suppressed all records to protect PII.
CTSCHED	character	CO-RX DAILY SCHEDULE	Collected at CRF.
CTDOSE	double	DOSE	Collected at CRF.
CTDOSE_U	character	DOSE UNIT	Collected at CRF.
CTIND_V	character	INDICATION (VERB.)	Suppressed all records to protect PII.
CTIND	character	INDICATION	Suppressed all records to protect PII.
CTPRIOR	character	CO-RX PRE-TRIAL	Collected at CRF.
CTFROM_D	double	CO-RX START DATE	Suppressed all records to protect PII.
CTFROM_C	character	CO-RX START CODE	Suppressed all records to protect PII.
CTONGO	character	CO-RX ONGOING	Collected at CRF.
CTTO_D	double	CO-RX END DATE	Suppressed all records to protect PII.
CTTO_C	character	CO-RX END CODE	Suppressed all records to protect PII.
ATCCODE	character	ATC CODE	Collected at CRF.
ATCTEXT	character	ATC TEXT	Collected at CRF.
RXWHONUM	character	WHO DRUG CODE	Suppressed all records to protect PII.
ATCCODE0	character	ATC CODE 0	Suppressed all records to protect PII.
ATCCODE1	character	ATC CODE 1	Suppressed all records to protect PII.

ATCCODE2	character	ATC CODE 2	Collected at CRF.
ATCCODE3	character	ATC CODE 3	Collected at CRF.
ATCCODE4	character	ATC CODE 4	Collected at CRF.
ATCCODE5	character	ATC CODE 5	Collected at CRF.
ATCCODE6	character	ATC CODE 6	Collected at CRF.
ATCCODE7	character	ATC CODE 7	Collected at CRF.
ATCCODE8	character	ATC CODE 8	Collected at CRF.
ATCCODE9	character	ATC CODE 9	Collected at CRF.
ATCTEXT0	character	ATC TEXT 0	Suppressed all records to protect PII.
ATCTEXT1	character	ATC TEXT 1	Suppressed all records to protect PII.
ATCTEXT2	character	ATC TEXT 2	Collected at CRF.
ATCTEXT3	character	ATC TEXT 3	Collected at CRF.
ATCTEXT4	character	ATC TEXT 4	Collected at CRF.
ATCTEXT5	character	ATC TEXT 5	Collected at CRF.
ATCTEXT6	character	ATC TEXT 6	Collected at CRF.
ATCTEXT7	character	ATC TEXT 7	Collected at CRF.
ATCTEXT8	character	ATC TEXT 8	Collected at CRF.
ATCTEXT9	character	ATC TEXT 9	Collected at CRF.
RXPREF	character	PREFERRED NAME	Suppressed all records to protect PII.
DCRFID	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification
DATCCODE0	Character	DE-IDENTIFIED ATC CODE 0	Masked some sensitive values
DATCTEXT0	Character	DE-IDENTIFIED ATC TEXT 0	Masked some sensitive values
DATCCODE1	Character	DE-IDENTIFIED ATC CODE 1	Masked some sensitive values
DATCTEXT1	Character	DE-IDENTIFIED ATC TEXT 1	Masked some sensitive values
DCTFROM_D	double	De-identified CO-RX START DATE	Applied subject specific randomly sampled offset to protect PII
DCTTO_D	double	De-identified CO-RX END DATE	Applied subject specific randomly sampled offset to protect PII

1.3.6.　　DEATH

Dataset	DEATH
Description	DEATH
Unique identifier	DCRFID

Variable	Type	Label	Comments
TRIAL	character	TRIAL ID.	Collected at CRF.
CRFID	character	CRF ID	Suppressed all records to protect PII.
DEATH_D	double	DEATH DATE	Suppressed all records to protect PII.
DTREAS	character	DEATH CAUSE	Collected at CRF.
DTREAS_V	character	DEATH CAUSE (VERB.)	Suppressed all records to protect PII.
DCRFID	integer	Patient number assigned for de-identification	Suppressed all records to protect PII.

1.3.7. DEVIATN

Dataset	DEVIATN
Description	DEVIATION
Unique identifier	DCRFID

Variable	Type	Label	Comments
TRIAL	character	TRIAL ID.	Collected at CRF.
CRFID	character	CRF ID	Suppressed all records to protect PII.
DEVIAT_V	character	DEVIATION (SPECIF.)	Suppressed all records to protect PII.
DEVIAT	character	DEVIATION	Collected at CRF.
ZDEVIAT	character	DEVIATION	Suppressed all records to protect PII.
DVTYPE	character	TYPE OF DEVIATION	Collected at CRF.
DCRFID	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification
DZDEVIAT	character	DE-IDENTIFED DEVIATION	Masked PII values. Retained non-PII values.

1.3.8. DIAGNOS

Dataset	DIAGNOS
Description	DIAGNOSIS
Unique identifier	DCRFID

Variable	Type	Label	Comments
TRIAL	character	TRIAL ID.	Collected at CRF.
CRFID	character	CRF ID	Suppressed all records to protect PII.
DXAXIS	character	AXIS	Collected at CRF.
DIAGN	character	DIAGNOSIS	Collected at CRF.
ZDIAGN	character	DIAGNOSIS	Collected at CRF.
DCRFID	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification

1.3.9. DISEASES

Dataset	DISEASES
Description	PREVIOUS AND CONCOMITANT DISEASES
Unique identifier	DCRFID

Variable	Type	Label	Comments
TRIAL	character	TRIAL ID.	Collected at CRF.
CRFID	character	CRF ID	Suppressed all records to protect PII.
DSSEQNO	double	SEQUENCE NUMBER	Collected at CRF.
DSSYSTEM	character	DISEASE BODY SYSTEM	Collected at CRF.
DSCOND	character	CONDITION	Collected at CRF.
DISEAS_V	character	DISEASE (VERB.)	Suppressed all records to protect PII.
DISEASE	character	DISEASE	Suppressed all records to protect PII.
DCRFID	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification

1.3.10. ECG

Dataset	ECG
Description	ELECTROCARDIOGRAM
Unique identifier	DCRFID

Variable	Type	Label	Comments
TRIAL	character	TRIAL ID.	Collected at CRF.
CRFID	character	CRF ID	Suppressed all records to protect PII.
ECG_D	double	ECG DATE	Suppressed all records to protect PII.
ECGSRCE	character	SOURCE ECG DATA	Collected at CRF.
EGLIMITS	character	ECG WITHIN NORMAL LIMITS	Collected at CRF.
EGRELCHA	character	CLIN. SIGNIFICANT CHANGES	Collected at CRF.
VISIT	double	VISIT	Collected at CRF.
EGADDSAM	character	ADDITIONAL SAMPLE	Collected at CRF.
DECG_D	Double	DE-IDENTIFIED ECG DATE	Applied subject specific randomly sampled offset to protect PII
DCRFID	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification

1.3.11.　ECGABN

Dataset	ECGABN
Description	ECG OTHER ABNORMALITIES
Unique identifier	DCRFID

Variable	Type	Label	Comments
TRIAL	character	TRIAL ID.	Collected at CRF.
CRFID	character	CRF ID	Suppressed all records to protect PII.
ECG_D	double	ECG DATE	Suppressed all records to protect PII.
ECG_T	double	ECG TIME	Collected at CRF.
ECGSRCE	character	SOURCE ECG DATA	Collected at CRF.
EASEQNO	double	SEQUENCE NUMBER	Collected at CRF.
ECGOTH_V	character	ECG OTHER ABN. (VERB.)	Suppressed all records to protect PII.
VISIT	double	VISIT	Collected at CRF.
DECG_D	double	DE-IDENTIFIED ECG DATE	Applied subject specific randomly sampled offset to protect PII
DCRFID	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification

1.3.12.   ECGEVAL

Dataset	ECGEVAL
Description	ELECTROCARDIOGRAM EVALUATION
Unique identifier	DCRFID

Variable	Type	Label	Comments
TRIAL	character	TRIAL ID.	Collected at CRF.
CRFID	character	CRF ID	Suppressed all records to protect PII.
ECG_D	double	ECG DATE	Applied subject specific randomly sampled offset to protect PII
ECG_T	double	ECG TIME	Collected at CRF.
ECGSRCE	character	SOURCE ECG DATA	Collected at CRF.
EEASPECT	character	ECG ASPECT	Collected at CRF.
EEEVAL	character	ECG EVALUATION	Suppressed all records to protect PII.
VISIT	double	VISIT	Collected at CRF.
DECG_D	double	DE-IDENTIFIED ECG DATE	Applied subject specific randomly sampled offset to protect PII
DCRFID	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification
DEEEVAL	character	DE-IDENTIFIED ECG EVALUATION	Replaced values with 'OTHER' to lower re-identification risk.

1.3.13. ECGPAR

Dataset	ECGPAR
Description	ELECTROCARDIOGRAM MEASUREMENTS
Unique identifier	DCRFID

Variable	Type	Label	Comments
TRIAL	character	TRIAL ID.	Collected at CRF.
CRFID	character	CRF ID	Suppressed all records to protect PII.
ECG_D	double	ECG DATE	Suppressed all records to protect PII.
ECG_T	double	ECG TIME	Collected at CRF.
ECGSRCE	character	SOURCE ECG DATA	Collected at CRF.
EPSEQNO	double	SEQUENCE NUMBER	Collected at CRF.
ECGPAR	character	ECG PARAMETER	Collected at CRF.
ECGVAL	double	ECG MEASUREMENT	Collected at CRF.
ECGPAR_U	character	ECG MEASUREMENT UNIT	Collected at CRF.
VISIT	double	VISIT	Collected at CRF.
DECG_D	double	DE-IDENTIFIED ECG DATE	Applied subject specific randomly sampled offset to protect PII
DCRFID	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification

1.3.14. ESRS

Dataset	ESRS
Description	EXTRAPYRAMIDAL SYMPTOM RATING SCALE
Unique identifier	DCRFID

Variable	Type	Label	Comments
TRIAL	character	TRIAL ID.	Collected at CRF.
CRFID	character	CRF ID	Suppressed all records to protect PII.
VISIT	double	VISIT	Collected at CRF.
ESGROUP	character	ESRS SUBGROUP	Collected at CRF.
ESITEM	character	ESRS ITEM	Collected at CRF.
ESSCORE	character	ESRS SCORE	Collected at CRF.
ZESSCORE	double	ESRS SCORE	Collected at CRF.
DCRFID	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification

1.3.15.   EVALINV

Dataset	EVALINV
Description	EVALUATION OF INJEC. SITES
Unique identifier	DCRFID

Variable	Type	Label	Comments
TRIAL	character	TRIAL ID.	Collected at CRF.
CRFID	character	CRF ID	Suppressed all records to protect PII.
VISIT	double	VISIT	Collected at CRF.
EITYPE	character	EVALUATION OF INJECT. TYPE	Collected at CRF.
EISITE	character	EVALUATION OF INJECT. SITE	Collected at CRF.
EISYMP	character	EVALUATION OF INJECT. SYMPTOM	Collected at CRF.
EISCORE	character	EVALUATION OF INJECT. SCORE	Collected at CRF.
DCRFID	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification

1.3.16. INEX

Dataset	INEX
Description	INCLUSION-EXCLUSION CRITERIA
Unique identifier	DCRFID

Variable	Type	Label	Comments
TRIAL	character	TRIAL ID.	Collected at CRF.
CRFID	character	CRF ID	Suppressed all records to protect PII.
IETYPE	character	TYPE OF SELECTION CRITERIA	Collected at CRF.
IECRIT	character	SELECTION CRITERIA	Collected at CRF.
ZIECRIT	double	SELECTION CRITERIA	Collected at CRF.
IEYN	character	ELIGIBILITY EXPR.	Suppressed all records to protect PII.
DCRFID DIEYN	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification Suppressed values corresponding to selection criteria revealing sensitive terms or PII

1.3.17. LABCOM

Dataset	LABCOM
Description	LAB COMMENTS
Unique identifier	DCRFID

Variable	Type	Label	Comments
TRIAL	character	TRIAL ID.	Collected at CRF.
CRFID	character	CRF ID	Suppressed all records to protect PII.
LABREFNO	character	LAB. REF.	Suppressed all records to protect PII.
SAMPLE_D	double	SAMPLING DATE	Suppressed all records to protect PII.
SAMPLE_T	double	SAMPLING TIME	Collected at CRF.
LABID	character	LAB. ID.	Suppressed all records to protect PII.
ZLABID	double	LAB. ID.	Suppressed all records to protect PII.
LABCOM	character	LAB COMMENTS	Suppressed all records to protect PII.
DSAMPLE_D	double	DE-IDENTIFIED SAMPLING DATE	Applied subject specific randomly sampled offset to protect PII
DCRFID	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification

1.3.18. LABNOR

Dataset	LABNOR
Description	LABORATORY NORMAL RANGES
Unique identifier	DCRFID

Variable	Type	Label	Comments
TRIAL	character	TRIAL ID.	Collected at CRF.
LABID	character	LAB. ID.	Suppressed all records to protect PII.
ZLABID	double	LAB. ID.	Suppressed all records to protect PII.
LABTEST	character	LAB. TEST	Collected at CRF.
ZLABTEST	character	LAB. TEST	Collected at CRF.
LNFROM_D	double	RANGE APPLICABLE FROM	Suppressed all records to protect PII.
LNTO_D	double	RANGE APPLICABLE TO	Suppressed all records to protect PII.
LNSEQNO	double	LAB. NORMAL SEQ.	Collected at CRF.
LABTST_U	character	LAB. TEST UNIT	Collected at CRF.
LABLOW	double	LOWER NORMAL LIMIT	Collected at CRF.
LABUPP	double	UPPER NORMAL LIMIT	Collected at CRF.
AGEFROM	double	LOWER AGE LIMIT	Collected at CRF.
AGETO	double	UPPER AGE LIMIT	Collected at CRF.
AGE_U	character	AGE UNIT	Collected at CRF.
WGHTFROM	double	LOWER WEIGHT LIMIT	Collected at CRF.
WGHTTO	double	UPPER WEIGHT LIMIT	Collected at CRF.
WGHT_U	character	WEIGHT UNIT	Collected at CRF.
SEX	character	SEX	Collected at CRF.

1.3.19.   LABREF

Dataset	LABREF
Description	LABORATORY REQUISITION NUMBERS
Unique identifier	DCRFID

Variable	Type	Label	Comments
TRIAL	character	TRIAL ID.	Collected at CRF.
CRFID	character	CRF ID	Suppressed all records to protect PII.
LABREFNO	character	LAB. REF.	Suppressed all records to protect PII.
LABID	character	LAB. ID.	Suppressed all records to protect PII..
ZLABID	double	LAB. ID.	Suppressed all records to protect PII.
LSRELCHA	character	CLIN. SIGNIFICANT CHANGES	Collected at CRF.
LFTYPE	character	TYPE OF SAMPLE	Collected at CRF.
DCRFID	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification

1.3.20. LABRES

Dataset	LABRES
Description	LABORATORY RESULTS
Unique identifier	DCRFID

Variable	Type	Label	Comments
TRIAL	character	TRIAL ID.	Collected at CRF.
CRFID	character	CRF ID	Suppressed all records to protect PII.
SAMPLE_D	double	SAMPLING DATE	Suppressed all records to protect PII.
SAMPLE_T	double	SAMPLING TIME	Collected at CRF.
LABID	character	LAB. ID.	Suppressed all records to protect PII.
ZLABID	double	LAB. ID.	Suppressed all records to protect PII.
LABTEST	character	LAB. TEST	Collected at CRF.
ZLABTEST	character	LAB. TEST	Collected at CRF.
LABVAL	double	LAB. TEST VALUE	Suppressed all records to protect PII.
LABVAL_V	character	LAB. TEST VALUE (VERB.)	Suppressed all records to protect PII.
LABLOW	double	LOWER NORMAL LIMIT	Collected at CRF.
LABUPP	double	UPPER NORMAL LIMIT	Collected at CRF.
LABTST_U	character	LAB. TEST UNIT	Collected at CRF.
LOWPATHO	double	LOWER PATHOLOGICAL LIMIT	Collected at CRF.
UPPPATHO	double	UPPER PATHOLOGICAL LIMIT	Collected at CRF.
CFACTOR	double	CONVERSION FACTOR	Collected at CRF.
SIUNIT	character	STANDARD INTERNATIONAL UNIT	Collected at CRF.
LABTSTNO	double	LAB. TEST NUMBER	Collected at CRF.
LABCLASS	character	LAB CLASS	Collected at CRF.
ENZYME	character	ENZYME	Collected at CRF.

			Applied subject specific randomly sampled offset to protect PII
DSAMPLE_D	double	DE-IDENTIFIED SAMPLING DATE	
DCRFID	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification
DLABVAL	Double	DE-IDENTIFIED LAB. TEST VALUE	Masked values corresponding to HCG and PROLACTIN Tests.

1.3.21. LABSAM

Dataset	LABSAM
Description	LABORATORY SAMPLES
Unique identifier	DCRFID

Variable	Type	Label	Comments
TRIAL	character	TRIAL ID.	Collected at CRF.
CRFID	character	CRF ID	Suppressed all records to protect PII.
SAMPLE_D	double	SAMPLING DATE	Suppressed all records to protect PII.
SAMPLE_T	double	SAMPLING TIME	Collected at CRF.
LABID	character	LAB. ID.	Suppressed all records to protect PII.
ZLABID	double	LAB. ID.	Suppressed all records to protect PII.
FASTED	character	SUBJECT FASTED	Collected at CRF.
HAEMOLYS	character	SAMPLE HAEMOLYSED	Collected at CRF.
LABREFNO	character	LAB. REF.	Suppressed all records to protect PII.
LSRELCHA	character	CLIN. SIGNIFICANT CHANGES	Collected at CRF.
DSAMPLE_D	double	DE-IDENTIFIED SAMPLING DATE	Applied subject specific randomly sampled offset to protect PII.
DCRFID	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification

1.3.22.   LABURI

Dataset	LABURI
Description	LABORATORY URINE RESULTS
Unique identifier	DCRFID

Variable	Type	Label	Comments
TRIAL	character	TRIAL ID.	Collected at CRF.
CRFID	character	CRF ID	Suppressed all records to protect PII.
SAMPLE_D	double	SAMPLING DATE	Suppressed all records to protect PII.
SAMPLE_T	double	SAMPLING TIME	Collected at CRF.
LABID	character	LAB. ID.	Suppressed all records to protect PII.
ZLABID	double	LAB. ID.	Suppressed all records to protect PII.
LABTEST	character	LAB. TEST	Collected at CRF.
ZLABTEST	character	LAB. TEST	Collected at CRF.
LUVAL	character	URINE VALUE	Collected at CRF.
LUVAL_V	character	URINE VALUE (VERB.)	Suppressed all records to protect PII.
LABTSTNO	double	LAB. TEST NUMBER	Collected at CRF.
LABCLASS	character	LAB CLASS	Collected at CRF.
DSAMPLE_D	double	DE-IDENTIFIED SAMPLING DATE	Applied subject specific randomly sampled offset to protect PII
DCRFID	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification

1.3.23.   PANSS

Dataset	PANSS
Description	POS. AND NEG. SYNDROM SCALE
Unique identifier	DCRFID

Variable	Type	Label	Comments
TRIAL	character	TRIAL ID.	Collected at CRF.
CRFID	character	CRF ID	Suppressed all records to protect PII.
VISIT	double	VISIT	Collected at CRF.
PAGROUP	character	PANSS SUBGROUP	Collected at CRF.
PAITEM	character	PANSS ITEM	Collected at CRF.
PASCORE	character	PANSS SCORE	Collected at CRF.
ZPASCORE	double	PANSS SCORE	Collected at CRF.
DCRFID	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification

1.3.24.   PHYSEXAM

Dataset	PHYSEXAM
Description	PHYSICAL EXAMINATION
Unique identifier	DCRFID

Variable	Type	Label	Comments
TRIAL	character	TRIAL ID.	Collected at CRF.
CRFID	character	CRF ID	Suppressed all records to protect PII.
VISIT	double	VISIT	Collected at CRF.

PESEQNO	double	SEQUENCE NUMBER	Collected at CRF.
PESYSTEM	character	PHYS. EXAM. BODY SYSTEM	Collected at CRF.
PERESULT	character	PHYS. EXAM. RESULT	Suppressed all records to protect PII.
EXAM_V	character	PHYS. EXAM. (VERB.)	Suppressed all records to protect PII.
EXAM	character	PHYS. EXAM.	Suppressed all records to protect PII.
DCRFID	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification
DPERESULT	character	PHYS. EXAM. RESULT	Masked values corresponding to sensitive body systems.

1.3.25. PK_FINAL

Dataset	PK_FINAL
Description	PHARMACOKINETICS
Unique identifier	DCRFID

Variable	Type	Label	Comments
CRFID	character	CRF ID	Suppressed all records to protect PII.
MDOSE	character	MODE DOSE	Collected at CRF.
PLASMA	double		Collected at CRF.
AMFROM_D	double	ADMIN. FROM DATE	Suppressed all records to protect PII.
AMFROM_T	double	ADMIN. FROM TIME	Collected at CRF.
AMFROM	double	DATE INJECTION BEFORE PLASMA SAMPLE	Suppressed all records to protect PII.
TTFROM_D	double	LAST CONTACT DATE	Applied subject specific randomly sampled offset to protect PII
TTTYPE	character	TERM. TYPE	Collected at CRF.
WEIGHT	double	WEIGHT	Suppressed all records to protect PII.
TRIAL	character	TRIAL ID.	Collected at CRF.

PLASMA_D	double	SAMPLING DATE	Suppressed all records to protect PII.
SAMPLE_T	double	SAMPLING TIME	Collected at CRF.
ALPUNIT	character	STANDARD INTERNATIONAL UNIT	Collected at CRF.
ALP	double	ALP, u/l	Collected at CRF.
ALTUNIT	character	STANDARD INTERNATIONAL UNIT	Collected at CRF.
ALT	double	ALT, u/l	Collected at CRF.
ASTUNIT	character	STANDARD INTERNATIONAL UNIT	Collected at CRF.
AST	double	AST, u/l	Collected at CRF.
CREUNIT	character	STANDARD INTERNATIONAL UNIT	Collected at CRF.
CREAT	double	CREAT, umol/l	Collected at CRF.
LDHUNIT	character	STANDARD INTERNATIONAL UNIT	Collected at CRF.
LDH	double	LDH, u/l	Collected at CRF.
TBUNIT	character	STANDARD INTERNATIONAL UNIT	Collected at CRF.
TB	double	TB, umol/l	Collected at CRF.
TPUNIT	character	STANDARD INTERNATIONAL UNIT	Collected at CRF.
TP	double	TP, g/l	Collected at CRF.
LABINTNO	character	BARC NR	Collected at CRF.
SPECIMEN	character	SPECIMEN	Collected at CRF.
CONCRIS	double	RIS, mg/ml	Collected at CRF.
CRIS_V	character	RIS_v	Collected at CRF.
CRIS_LOQ	character	RIS_LOQ	Collected at CRF.
CONC9OH	double	9-OH-RIS, ng/ml	Collected at CRF.
C9OH_V	character	9-OH-RIS_v	Collected at CRF.
C9OH_LOQ	character	9-OH-RIS_LOQ	Collected at CRF.
ACT_M	double	Active Moiety,(ng/ml)	Collected at CRF.
VISIT	double	VISIT	Collected at CRF.
VISIT_D	double	VISIT DATE	Suppressed all records to protect PII.
PLREFNO	double	PLASMA REF. NO.	Suppressed all records to protect PII.
PLASMA_T	double	TIME OF PLASMA SAMPLING	Collected at CRF.
LABREFNO	character	LAB. REF.	Suppressed all records to protect PII.

AMFROM_O	double	ADMIN. FROM DATE	Suppressed all records to protect PII.
AMTO_O	double	ADMIN. TO DATE	Suppressed all records to protect PII.
ZAMDOSE	double	DOSE	Collected at CRF.
LORAL_D	double	LAST ORAL INTAKE DATE	Collected at CRF.
DIFFB_H	double	DIFF. PLASMA AND INJECTION BEFORE (HOUR)	Collected at CRF.
DIFFB_D	double	DIFF. PLASMA AND INJECTION BEFORE (DAY)	Collected at CRF.
DIFFO	double	DIFF. PLASMA AND ORAL INTAKE	Collected at CRF.
DPLASMA	double	DE-IDENTIFIED PLASMA	Collected at CRF.
DPLASMA_D	double	DE-IDENTIFIED SAMPLING DATE	Applied subject specific randomly sampled offset to protect PII
DAMFROM	double	DE-IDENTIFIED DATE INJECTION BEFORE PLASMA SAMPLE	Collected at CRF.
DAMFROM_D	double	DE-IDENTIFIED ADMIN. FROM DATE	Applied subject specific randomly sampled offset to protect PII
DAMFROM_O	double	DE-IDENTIFIED ADMIN. FROM DATE	Collected at CRF.
DAMTO_O	double	DE-IDENTIFIED ADMIN. TO DATE	Collected at CRF.
DVISIT_D	double	DE-IDENTIFIED VISIT DATE	Applied subject specific randomly sampled offset to protect PII
DLORAL_D	double	DE-IDENTIFIED LAST ORAL INTAKE DATE	Collected at CRF.
DCRFID	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification

1.3.26. PLAADM

Dataset	PLAADM
Description	DRUG ADMINISTRATION FOR PLASMA
Unique identifier	DCRFID

Variable	Type	Label	Comments
TRIAL	character	TRIAL ID.	Collected at CRF.
CRFID	character	CRF ID	Suppressed all records to protect PII.
PLREFNO	double	PLASMA REF. NO.	Suppressed all records to protect PII.
PLADM_D	double	DRUG ADMIN. DATE	Suppressed all records to protect PII.
PLADM_T	double	DRUG ADMIN. TIME	Collected at CRF.
PLADMSEQ	character	DRUG ADMIN. SEQ.	Collected at CRF.
DPLADM_D	double	DE-IDENTIFIED DRUG ADMIN. DATE	Applied subject specific randomly sampled offset to protect PII
DCRFID	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification

1.3.27. PLASAM

Dataset	PLASAM
Description	PLASMA SAMPLES
Unique identifier	DCRFID

Variable	Type	Label	Comments
TRIAL	character	TRIAL ID.	Collected at CRF.
CRFID	character	CRF ID	Suppressed all records to protect PII.
PLREFNO	double	PLASMA REF. NO.	Suppressed all records to protect PII.
PLASMA_D	double	DATE OF PLASMA SAMPLING	Suppressed all records to protect PII.
PLASMA_T	double	TIME OF PLASMA SAMPLING	Collected at CRF.
LABREFNO	character	LAB. REF.	Suppressed all records to protect PII.
LABINTNO	character	LABORATORY INTERNAL NO.	Suppressed all records to protect PII.
VISIT	character	VISIT	Collected at CRF.
DPLASMA_D	double	DE-IDENTIFIED DATE OF PLASMA SAMPLING	Applied subject specific randomly sampled offset to protect PII
DCRFID	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification

1.3.28. PRETHER

Dataset	PRETHER
Description	PREVIOUS THERAPY
Unique identifier	CRFID

Variable	Type	Label	Comments
TRIAL	character	TRIAL ID.	Collected at CRF.
CRFID	character	CRF ID	Suppressed all records to protect PII.
PTTYPE	character	PREV. RX TYPE	Collected at CRF.
PTSEQNO	double	PREV. RX SEQ.	Suppressed all records to protect PII.
PRVRX_V	character	PREV. RX (VERB.)	Suppressed all records to protect PII.
PRVRX	character	PREV. RX	Suppressed all records to protect PII.
PTSCHED	character	PREV. RX DAILY SCHEDULE	Collected at CRF.
PTADM_D	double	PREV. RX LAST INJEC./ADMIN. DATE	Suppressed all records to protect PII.
PTADM_C	character	PREV. RX LAST INJEC./ADMIN. CODE	Suppressed all records to protect PII.
PTFROM_D	double	PREV. RX START DATE	Suppressed all records to protect PII.
PTFROM_C	character	PREV. RX START CODE	Suppressed all records to protect PII.
PTTO_D	double	PREV. RX END DATE	Suppressed all records to protect PII.
PTTO_C	character	PREV. RX END CODE	Suppressed all records to protect PII.
PTAE_V	character	PREV. RX AE (VERB.)	Suppressed all records to protect PII.
RXWHONUM	character	WHO DRUG CODE	Suppressed all records to protect PII.
ATCCODE0	character	ATC CODE 0	Collected at CRF.
ATCCODE1	character	ATC CODE 1	Collected at CRF.
ATCCODE2	character	ATC CODE 2	Collected at CRF.
ATCCODE3	character	ATC CODE 3	Collected at CRF.
ATCCODE4	character	ATC CODE 4	Collected at CRF.

ATCCODE5	character	ATC CODE 5	Collected at CRF.
ATCCODE6	character	ATC CODE 6	Collected at CRF.
ATCCODE7	character	ATC CODE 7	Collected at CRF.
ATCCODE8	character	ATC CODE 8	Collected at CRF.
ATCCODE9	character	ATC CODE 9	Collected at CRF.
ATCTEXT0	character	ATC TEXT 0	Collected at CRF.
ATCTEXT1	character	ATC TEXT 1	Collected at CRF.
ATCTEXT2	character	ATC TEXT 2	Collected at CRF.
ATCTEXT3	character	ATC TEXT 3	Collected at CRF.
ATCTEXT4	character	ATC TEXT 4	Collected at CRF.
ATCTEXT5	character	ATC TEXT 5	Collected at CRF.
ATCTEXT6	character	ATC TEXT 6	Collected at CRF.
ATCTEXT7	character	ATC TEXT 7	Collected at CRF.
ATCTEXT8	character	ATC TEXT 8	Collected at CRF.
ATCTEXT9	character	ATC TEXT 9	Collected at CRF.
RXPREF	character	PREFERRED NAME	Suppressed all records to protect PII.
DPTADM_D	double	DE-IDENTIFIED PREV. RX LAST INJEC./ADMIN. DATE	Applied subject specific randomly sampled offset to protect PII
DPTFROM_D	double	DE-IDENTIFIED PREV. RX START DATE	Applied subject specific randomly sampled offset to protect PII
DPTTO_D	double	DE-IDENTIFIED PREV. RX END DATE	Applied subject specific randomly sampled offset to protect PII
DCRFID	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification

1.3.29. RELAE

Dataset	RELAE
Description	RELATED AES FOR TERMINATION OR DEATH
Unique identifier	DCRFID

Variable	Type	Label	Comments
TRIAL	character	TRIAL ID.	Collected at CRF.
CRFID	character	CRF ID	Suppressed all records to protect PII.
RATYPE	character	AE CONSEQUENCE	Suppressed all records to protect PII.
AESEQNO	double	AE SEQ.	Collected at CRF.
DCRFID	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification
DRATYPE	character	DE-IDENTIFIED AE CONSEQUENCE	Suppressed some values to protect PII.

1.3.30. RELATED

Dataset	RELATED
Description	RELATED
Unique identifier	DCRFID

Variable	Type	Label	Comments
TRIAL	character	TRIAL ID.	Collected at CRF.
CRFID	character	CRF ID	Suppressed all records to protect PII.
RELCRFID	character	RELATED CRF ID.	Suppressed all records to protect PII.
RLINV	character	INVEST. BOOKLET LINK	Collected at CRF.
ZRLINV	double	INVEST. BOOKLET LINK	Collected at CRF.

| DCRFID | integer | Patient number assigned for de-identification | Randomly assigned patient number for de-identification |

1.3.31.   TOTALD

Dataset	TOTALD
Description	TOTALD
Unique identifier	DCRFID

Variable	Type	Label	Comments
TRIAL	character	TRIAL ID.	Collected at CRF.
CRFID	character	CRF ID	Suppressed all records to protect PII.
VISIT	double	VISIT	Collected at CRF.
TOGROUP	character	TOTAL GROUP	Collected at CRF.
TOITEM	character	TOTAL ITEM	Collected at CRF.
TOSCORE	double	TOTAL SCORE	Collected at CRF.
DCRFID	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification

1.3.32. TRLREGM

Dataset	TRLREGM
Description	TRIAL MEDICATION REGIMENS
Unique identifier	NA

Variable	Type	Label	Comments
TRIAL	character	TRIAL ID.	Collected at CRF.
RANDGRP	character	RANDOMISATION GROUP	Collected at CRF.
PHASE	character	TRIAL PHASE	Collected at CRF.
SEGMENT	double	TRIAL SEGMENT SEQ.	Collected at CRF.
BOX	character	BOX	Collected at CRF.
TREAT	character	TREATMENT	Collected at CRF.
FORMULAT	character	FORMULATION	Collected at CRF.
STRENGTH	double	STRENGTH OF 1 UNIT	Collected at CRF.
STRENG_U	character	STRENGTH UNIT	Collected at CRF.
NUMFORM	double	UNITS PER ADMIN.	Collected at CRF.
TMFREQ	character	ADMIN. FREQ.	Collected at CRF.
TMROUTE	character	ADMIN. ROUTE	Collected at CRF.
ZTMROUTE	character	ADMIN. ROUTE	Collected at CRF.
TMDUR	double	SEGMENT DURATION	Collected at CRF.
TMDUR_U	character	DURATION UNIT	Collected at CRF.
BLINDING	character	BLINDING	Collected at CRF.

1.3.33. TRLTERM

Dataset	TRLTERM
Description	TRIAL TERMINATION REASON
Unique identifier	DCRFID

Variable	Type	Label	Comments
TRIAL	character	TRIAL ID.	Collected at CRF.
CRFID	character	CRF ID	Suppressed all records to protect PII.
TTTYPE	character	TERM. TYPE	Collected at CRF.
TTFROM_D	double	LAST CONTACT DATE	Suppressed all records to protect PII.
TTREAS	character	TERM. REASON	Suppressed all records to protect PII.
TTREAS_V	character	TERM. REASON (VERB.)	Suppressed all records to protect PII.
DTTFROM_D	double	DE-IDENTIFIED LAST CONTACT DATE	Applied subject specific randomly sampled offset to protect PII
DCRFID	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification
DTTREAS	character	DE-IDENTIFIED TERM. REASON	Suppressed some records to protect PII

1.3.34. VISIT

Dataset	VISIT
Description	VISITS
Unique identifier	DCRFID

Variable	Type	Label	Comments
TRIAL	character	TRIAL ID.	Collected at CRF.
CRFID	character	CRF ID	Suppressed all records to protect PII.
VISIT	double	VISIT	Collected at CRF.
VISIT_D	double	VISIT DATE	Suppressed all records to protect PII.
INIESRS	character	ESRS RATER'S INITIALS	Suppressed all records to protect PII.
INIPANSS	character	PANNS RATER'S INITIALS	Suppressed all records to protect PII.
CGI	character	CLINICAL GLOBAL IMPRESSION	Collected at CRF.
VASPAIN	double	VAS SCORE	Collected at CRF.
UNSREAS	character	REASON UNSCHEDULED VISIT?	Collected at CRF.
DCRFID DVISIT_D	integer double	Patient number assigned for de-identification DE-IDENTIFIED VISIT DATE	Randomly assigned patient number for de-identification Applied subject specific randomly sampled offset to protect PII

1.3.35.   VITSIGN

Dataset	VITSIGN
Description	VITAL SIGNS
Unique identifier	CRFID

Variable	Type	Label	Comments
TRIAL	character	TRIAL ID.	Collected at CRF.
CRFID	character	CRF ID	Suppressed all records to protect PII.
VISIT	double	VISIT	Collected at CRF.
POSITION	character	POSITION	Collected at CRF.
PULSE	double	PULSE, beats/min	Collected at CRF.
SBP	double	SYSTOLIC BP, mmHg	Collected at CRF.
DBP	double	DIASTOLIC BP, mmHg	Collected at CRF.
WEIGHT	double	WEIGHT	Suppressed to protect PII
WEIGHT_U	character	WEIGHT UNIT	Collected at CRF.
DWEIGHT	double	De-identified WEIGHT	Randomly sampled weight at screening within group to protect PII. Retained change in weight.
DWEIGHTGP	character	WEIGHT GROUP	Aggregated to 3 groups to protect PII
DCRFID	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification